

CLAIMS

1. A stabilized liquid pharmaceutical composition comprising an interferon (IFN) or an isoform, mutein, fused protein, functional derivative, active fraction or salt thereof, wherein said formulation is a solution that comprises a buffer, 2-hydroxypropyl-beta-cyclodextrin, an isotonicity agent and an anti-oxidant.
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2. The composition according to claim 1, wherein said interferon is IFN-beta.
3. The composition according to claims 1 or 2, wherein said IFN-beta is recombinant human IFN-beta.
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4. The composition according to any of the preceding claims, wherein said buffer is present in an amount sufficient to maintain the pH of said composition within plus or minus 0.5 units of a specified pH, where the specified pH is about 3 to about 6.
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5. The composition according to any of the preceding claim, wherein said pH is 3.8.
6. The composition according to any of the preceding claims, wherein said buffer is present at a concentration of about 5 mM to 500 mM.
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7. The composition according to any of the preceding claims, wherein said buffer is present at a concentration of about 50 mM.
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8. The composition according to any of the preceding claims, wherein the buffer is acetate buffer.
9. The composition according to any of the preceding claims, wherein said isotonicity agent is mannitol.
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10. The composition according to any of the preceding claims, wherein said isotonicity agent is present at a concentration of about 0.5 mg/ml to about 500 mg/ml.

11. The composition according to any of the preceding claims, wherein said isotonicity agent is present at a concentration of about 50 mg/ml.
- 5 12. The composition according to any of the preceding claims, wherein said the antioxidant is methionine.
13. The composition according to any of the preceding claims, wherein said the antioxidant is present at a concentration of about 0.01 to about 5 mg/ml.
- 10 14. The composition according to any of the preceding claims, wherein said the antioxidant is present at a concentration of about 0.1 mg/ml.
- 15 15. The composition according to any of the preceding claims, wherein said interferon is present at a concentration of about 10 µg/ml to about 800 µg/ml.
16. The composition according to any of the preceding claims, wherein said cyclodextrin is present at a molar ratio vs. interferon of from 500-fold molar excess up to 700-fold molar excess.
- 20 17. The composition according to any of the preceding claims, wherein said interferon is present at a concentration of about 44, 88 or 276 µg/ml.
- 25 18. The composition according to any of the preceding claims, wherein said composition is an aqueous solution.
19. The composition according to any of the preceding claims, further comprising a bacteriostatic agent.
- 30 20. The composition according to any of the preceding claims, wherein said bacteriostatic agent is benzyl alcohol.
21. The composition according to any of the preceding claims, wherein said bacteriostatic agent is present at a concentration of about 0.1% to about 2%.

22. The composition according to any of the preceding claims, wherein said bacteriostatic agent is present at a concentration of about 0.2 or 0.3%.

5 23. The composition according to any of the preceding claims, wherein the isotonicity agent is mannitol, the anti-oxidant is methionine and the interferon is interferon beta.

24. The composition according to any of the preceding claims wherein the composition is the following liquid formulation:

Interferon beta-1a	44	µg/mL
HPBCD	1.9	mg/mL
Methionine	0.1	mg/mL
Mannitol	50	mg/mL
acetate buffer up to	1	mL

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25. A method for preparing a stabilized liquid pharmaceutical composition according any of claims 1 to 24, wherein said method comprises adding a calculated amounts of 2-hydroxypropyl-beta-cyclodextrin, antioxidant and isotonicity agent to the buffered solution and then adding the interferon (IFN) or an isoform, mutein, fused protein, functional derivative, active fraction or salt thereof.

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26. A container hermetically sealed in conditions sterile and appropriate for storage prior to use, comprising the liquid pharmaceutical formulation according to any according to any of claims 1 to 24.

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27. The container according to claim 26, wherein said container is a pre-filled syringe for mono-dose administration.

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28. The container according to claim 26, wherein said container is a vial.

29. The container according to claim 26, wherein said container is a cartridge for an auto-injector.

30. The container according any of claims 26 to 29, wherein said container is for mono-dose or multi-dose administration.

5 31. A kit for multi-dose administration of a pharmaceutical composition according to any of claims 26 to 29, wherein the kit comprises a first container filled with a pharmaceutical composition according to any of claims 1 to 24 and a second cartridge filled of a solution of the bacteriostatic agent.